

CLAIMS

1. An aqueous pharmaceutical composition comprising:
5 from 1 to 100 mg/mL of a fluoroquinolone active agent;
from 0 to 100 mg/mL of a steroidal or non-steroidal anti-inflammatory agent;
from 1 to 50% by weight of cyclodextrin;
from 0.1 to 25 molar equivalents of a hydroxy acid;
from 0 to 20% by weight of a co-solubilizer; and
10 water to balance,
said formulation having a pH between 4 and 7.
2. The composition according to claim 1, wherein said cyclodextrin is selected from the group consisting of α cyclodextrins, β cyclodextrins, γ cyclodextrins, and δ cyclodextrins.
- 15 3. The composition according to claim 1, wherein said cyclodextrin is selected from the group consisting of sulfoalkylether cyclodextrins and hydroxyalkyl cyclodextrins.
4. The composition according to claim 1, wherein said hydroxy acid is selected from the group consisting of citric acid, ascorbic acid, malic acid, and tartaric acid.
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5. The composition according to claim 1, further comprising from 0.001 to 2 percent by weight of a preservative.
6. The composition according to claim 1, further comprising a preservative selected from the group consisting of chlorobutanol, sorbic acid, and EDTA.
- 25 7. The composition according to claim 1, further comprising: from 0.05 to 5 % by weight of a soluble polymer.
8. The composition according to claim 7, wherein said soluble polymer is selected from the group consisting of methylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, polyvinyl alcohol, and poloxamers.
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9. The composition according to claim 1, wherein said fluoroquinolone is selected from the group consisting of Gatifloxacin, Moxifloxacin, Sitafloracin, Lomefloxacin, Grepafloxacin, Gemifloxacin, Norfloxacin,

- Ofloxacin, Levofloxacin, Trovafloxacin, Ciprofloxacin and combinations thereof.
10. The composition according to claim 1, wherein said steroidal or non-steroidal anti-inflammatory compound is a steroidal compound and is selected from the group consisting of cortisone, hydrocortisone, corticosterone, deoxycorticosterone, prednisolone, methylprednisolone, meprednisone, triamcinolone, paramethasone, fluprednisolone, betamethasone, dexamethazone, fludrocortisone, and combinations thereof.
11. The composition according to claim 1, wherein said steroidal or non-steroidal anti-inflammatory compound is a non-steroidal compound and is selected from the group consisting of aspirin, diclofenac, indomethacin, sulindac, ketoprofen, flurbiprofen, ibuprofen, naproxen, piroxicam, tenoxicam, tolmetin, ketorolac, oxaprosin, mefenamic acid, fenoprofen, nambumetone, acetaminophen, nimesulide, NS-398, flosulid, L-745337, celecoxib, rofecoxib, SC-57666, DuP-697, parecoxib sodium, JTE-522, valdecoxib, SC-58125, etoricoxib, RS-57067, L-748780, L-761066, APHS, etodolac, meloxicam, and S-2474, and combinations thereof.
12. A method of treating a bacterial infection of an eye of a subject in need thereof, comprising topically administering a formulation according to claim 1 to the eye of said subject in an amount effective to treat said bacterial infection.
13. A pharmaceutical formulation comprising:
from 1 to 100 mg/mL of a fluoroquinolone active agent;
from 0 to to 100 mg/mL of a steroidal or non-steroidal anti-inflammatory agent;
from 1 to 50% by weight of cyclodextrin;
from 0.1 to 25 molar equivalents of a hydroxy acid.
14. A pharmaceutical formulation according to claim 13 in lyophilized form which when reconstituted with water produces an aqueous pharmaceutical composition having a pH between 4.5 and 7 and comprising:
from 1 to 100 mg/mL of a fluoroquinolone active agent;
from 1 to 50% by weight of cyclodextrin;
from 0.1 to 25 molar equivalents of a hydroxy acid; and water to balance.
15. The composition according to claim 13, wherein said cyclodextrin is selected

from the group consisting of α cyclodextrins, β cyclodextrins, γ cyclodextrins, and δ cyclodextrins.

16. The composition according to claim 13, wherein said cyclodextrin is selected from the group consisting of sulfoalkylether cyclodextrins and hydroxyalkyl cyclodextrins.
17. The composition according to claim 13, wherein said hydroxy acid is selected from the group consisting of citric acid, ascorbic acid, malic acid, and tartaric acid.
18. The composition according to claim 13, further comprising from 0.001 to 2 percent by weight of a preservative.
19. The composition according to claim 18, said preservative selected from the group consisting of chlorobutanol, sorbic acid, and EDTA.
20. The composition according to claim 14, further comprising: from 0.05 to 5 % by weight of a soluble polymer.
21. The composition according to claim 21, wherein said soluble polymer is selected from the group consisting of methylcellulose, carboxymethylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, polyvinyl alcohol, and poloxamers.
22. The composition according to claim 13, wherein said fluoroquinolone is selected from the group consisting of Gatifloxacin, Moxifloxacin, Sitafloxacin, Lomefloxacin, Grepafloxacin, Gemifloxacin, Norfloxacin, Ofloxacin, Levofloxacin, Trovafloxacin, Ciprofloxacin and combinations thereof.
23. The composition according to claim 13, wherein said steroidal or non-steroidal anti-inflammatory compound is a steroidal compound and is selected from the group consisting of cortisone, hydrocortisone, corticosterone, deoxycorticosterone, prednisolone, methylprednisolone, meprednisone, triamcinolone, paramethasone, fluprednisolone, betamethasone, dexamethazone, fludrocortisone, and combinations thereof.
24. The composition according to claim 13, wherein said steroidal or non-steroidal anti-inflammatory compound is a non-steroidal compound and is selected from the group consisting of aspirin, diclofenac, indomethacin, sulindac, ketoprofen, flurbiprofen, ibuprofen, naproxen, piroxicam,

- tenoxicam, tolmetin, ketorolac, oxaprosin, mefenamic acid, fenoprofen, nambumetone, acetaminophen, nimesulide, NS-398, flosulid, L-745337, celecoxib, rofecoxib, SC-57666, DuP-697, parecoxib sodium, JTE-522, valdecoxib, SC-58125, etoricoxib, RS-57067, L-748780, L-761066, APHS, etodolac, meloxicam, and S-2474, and combinations thereof. thereof.
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25. In a method of topically applying a pharmaceutical composition containing an active compound to the eye of a subject in need thereof, which active compound precipitates from said composition on the cornea of said subject, the improvement comprising: including a soluble polymer in said
- 10 composition in an amount effective to reduce the precipitation of said active compound on the cornea of said subject.
26. The method according to claim 25, wherein said soluble polymer is selected from the group consisting of methylcellulose, carboxymethylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, and polyvinyl alcohol,
- 15 and poloxamers.
27. The method according to claim 25, wherein said active compound is a fluoroquinolone.
28. The method according to claim 25, said pharmaceutical composition further comprising a steroidal or non-steroidal anti-inflammatory compound.
- 20 29. In a topical pharmaceutical composition containing an active compound used to topically apply said active compound to the eye of a subject in need thereof, which active compound precipitates from said composition on the cornea of said subject, the improvement comprising: including from 0.05 to 5% by weight of a soluble polymer in said composition in an amount
- 25 effective to reduce the precipitation of said active compound on the cornea of said subject.
30. The composition according to claim 29, wherein said soluble polymer is selected from the group consisting of methylcellulose, carboxymethylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, and polyvinyl alcohol, and poloxamers.
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31. The composition according to claim 29, wherein said active compound is a fluoroquinolone.
32. The composition according to claim 29, said composition further comprising a steroidal or non-steroidal anti-inflammatory compound.